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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,361	03/11/2004	Peter William Gage	17136-002RE1	7939
26181	7590	06/13/2005	EXAMINER	
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			FOLEY, SHANON A	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/800,361

Applicant(s)

GAGE ET AL

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-23 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/269,278.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

RD

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DETAILED ACTION

Please note that the Certificate of Correction has not been entered into the body of the application as submitted. Please make this correction. Applicant is reminded that underlining is not permitted in the Certificate of Correction as it is considered part of the original body of the patent.

Oath/Declaration

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The preliminary amendment states that the claims are being broadened. In the case of broadening, all inventors are required to sign the oath, see 37 CFR 1.172.

35 U.S.C. 251

Claims 1-23 are rejected under 35 U.S.C. 251 as being improperly broadened in a reissue application made and sworn to by the assignee and not the patentee. A claim is broader in scope than the original claims if it contains within its scope any conceivable product or process which would have infringed the original patent. A claim is broadened if it is broader in any one respect even though it may be narrower in other respects.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 9, 11, 12, 14, 16, 17, 19, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harpold et al. (US 5,846,757) and Schubert et al. (American Society for Microbiology. 1995, page 63).

The claims are drawn screening method to determine ion channel modulating activity of a test substance by:

- contacting a host cell, *E. coli*, expressing heterologous protein, HIV Vpu, having ion channel activity in the plasma membrane with a test substance and
- determining changes to ion channel activity by detecting the effect of the test substance on the net movement of metabolite molecules across the plasma membrane.

Harpold et al. teach a method of identifying a compound that modulates the activity of a calcium channel by contacting a eukaryotic cell or *E. coli* expressing a heterologous calcium channel protein with a test substance and determining whether the compound modulates the activity of the heterologous calcium channel and the permeability of the cell plasma membrane. See column 4, line 60 to column 7, line 60, column 12, line 45 to column 14, line 8, column 19, line 13 to column 24, line 12 and claim 1.

Harpold et al. do not teach HIV Vpu.

However, Schubert et al. teach heterologous HIV-1 Vpu ion channel activity in artificial lipid bilayers, see the meeting abstract provided.

One of ordinary skill in the art at the time the invention was made would have been motivated to heterologously express the HIV-1 Vpu of Schubert et al. in the method of Harpold et al. to elucidate the effects HIV-1 infection has on cellular ion channel function, see the

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teachings of Schubert et al. and identify compounds that modulate HIV-1 Vpu ion channel activity, see the teachings of Harpold et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for using the HIV-1 Vpu of Schubert et al. as the heterologous ion channel protein in the method of Harpold et al. because Schubert et al. heterologously express HIV-1 Vpu into an artificial lipid bilayers that mimics the plasma membrane of a cell.

Claims 13, 18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harpold et al. and Schubert et al. as applied to claims 9, 11, 12, 14, 16, 17, 19, 21 and 22 above, and further in view of Tribe (US 4,681,852).

The claims are drawn to detecting leakage of metabolites by cross-feeding of cells which are auxotrophic for the leaked metabolite or failure of the cells expressing the ion channel to grow in the absence of the leaking metabolite supplied in the external medium.

See the teachings of Harpold et al. and Schubert et al. above. Neither reference teaches cross-feeding cells or failure of cells to grow in the absence of the leaking metabolite supplied in the external medium.

However, Tribe teaches cross-feeding auxotrophs to screen for cells having specific transport system mutations; see column 18, line 62 to column 19, line 5, column 29, line 64 to column 30, line 30 and column 59, lines 16-41.

One of ordinary skill in the art at the time the invention was made would have been motivated to detect the leakage of metabolites in the method of Harpold et al. by cross-feeding autotrophic cells because Tribe teaches that this technique is specifically useful for identifying mutant cells with a particular loss of a relevant transport system, see the previous citations. One

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of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for cross-feeding the auxotrophs of Harpold et al. by the method of Tribe because Harpold et al. teach cells comprising various subunits of heterologous calcium channels that affect calcium transport, see column 14, line 25 to column 22, line 42. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Allowable Subject Matter

Claims 1-8 are drawn to allowable subject matter. The prior art does not teach or suggest monitoring metabolites that do not directly permeate the ion channel formed by a heterologous protein in the plasma membrane of the cell.

In addition, claims 10, 15 and 20 are also drawn to allowable subject matter. The claims are drawn to determining the effect of permeability of proline or adenine across the plasma membrane. One of ordinary skill in the art at the time the invention was made would not have had a reasonable expectation of detecting the influx of proline or adenine into and out of a cell through the heterologous HIV-1 Vpu of Schubert et al. because it was unknown that proline or adenine passed through the HIV-1 Vpu channel at the time the invention was made. Schubert et al. only teach that HIV-1 Vpu has ion channel activity. The reference does not teach which ions pass through the channel and since neither proline nor adenine are ions, it would not be expected that these molecules would be conveyed through the Vpu ion channel.


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-Th 6:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley
Primary Examiner
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